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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. P04829US1 10/007,866 12/06/2001 Vijay Kumar 07/24/2003 MCKEE, VOORHEES & SEASE, P.L.C. **EXAMINER 801 GRAND AVENUE** WHITE, EVERETT NMN **SUITE 3200** DES MOINES, IA 50309-2721 ART UNIT PAPER NUMBER 1623 DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/007,866	KUMAR ET AL.
	Examiner	Art Unit
	EVERETT WHITE	1623
The MAILING DATE of this communicatio		
Period f r Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1)☐ Responsive to communication(s) filed or		•
2a)☐ This action is FINAL. 2b)⊠	This action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims	alta a	
4) Claim(s) 1-35 is/are pending in the applic		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) <u>1-35</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement. Application Papers		
9)☐ The specification is objected to by the Exa	miner.	
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12)☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No.		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-94 3) Information Disclosure Statement(s) (PTO-1449) Paper N	8) 5) Notice	ew Summary (PTO-413) Paper No(s) of Informal Patent Application (PTO-152)
U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Offi	ce Action Summary	Part of Paper No. 3

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DETAILED ACTION

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 13-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 13 fails to set forth any steps involved in the method/process and it is unclear what method/process applicant intends to accomplish. Claims 14-35 are also rejected since these claims depend from Claim 13 and do not clarify the process steps intended for Claim 13.

Claims 14, 16, 18, 22, 24, 26, 30 and 31 recites the limitation "an acylating step" in Claim 13. There is insufficient antecedent basis for this limitation in the claims since Claim 13 fails to recite an acylating step. Claims 15, 17, 19-21, 23, 25, and 27-29 are also rejected since these claims depend from Claims 14, 16, 18, 22, 24 and 26.

Claims 32-34 recite further steps that may be carried out after the initial step(s) of Claim 13. However, these claims are indefinite since Claim 13 fails to set forth the initial step(s).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-5 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogan et al (US Patent No. 4,590,265).

Applicants claim a biodegradable, oxidized cellulose ester. Additional limitations in the dependent claims include: the oxidized cellulose ester having a specific carboxyl content; the oxidized cellulose ester having a specific formula; the oxidized cellulose ester being subjected to specific process conditions and having specific properties such as being dried, being present in a monolithic transparent film, a biodegradable coating, a pharmaceutical, an agricultural product, a veterinary composition, and being soluble in specific solvents.

The Bogan et al patent discloses a chemical modification of a cellulose ester by oxidizing the primary hydroxyl group at the Co position of the anhydroglucose ring of the cellulose ester to produce a carboxylated cellulose ester (see column 17, lines 44-50), which meets the carboxyl content set forth in the instant claims. See the structure of the carboxylated cellulose acetate butyrate at the bottom of column 16 of the Bogan et al patent, which anticipates the oxidized cellulose ester of formula I set forth in instant Claim 4 when X represents H; w is 1; R represents (CH₂)_nCH₃, n is 1 or 2; and when x is 0.1-2. The Bogan et al patent also anticipates the oxidized cellulose ester of formula II set forth in instant Claim 4 when X represents H; w is 1; R' and/or R" represents (CH₂)_nCH₃, n is 1 or 2; and when x & y are 0.1-1.9. The Limitation in the instant claims regarding a process step wherein the oxidized cellulose ester is dried is noted, but do not make the claimed oxidized cellulose ester patentable since process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. In re Thorpe et al. (CAFC 1985), supra; In re Dike (CCPA 1968) 394 F2d 584, 157 USPQ 581; Tri-Wall Containers, Inc. v. United States et al. (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; In re Brown et al. (CCPA 1972) 450 F2d 531, 173 USPQ 685; Ex parte Edwards et al. (BPAI 1986) 231 USPQ 981. Limitations in the instant claims regarding the presence of the oxidized cellulose in a monolithic transparent film, a biodegradable coating, a pharmaceutical, an agricultural product, or a veterinary composition are noted, but do not make the claimed oxidized cellulose ester patentable since a difference in intended use cannot render a claimed composition novel. Note In

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re Tuominen, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. With regard to the instantly claimed oxidized cellulose ester being biodegradable and soluble in specific solvents, Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Accordingly, the above described carboxylated cellulose ester of the Bogan et al patent anticipates the instantly claimed biodegradable, oxidized cellulose ester for the reasons set forth herein.

5. Claims 1 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (US Patent No. 5,973,139).

Applicants claim a biodegradable, oxidized cellulose ester and a dependent claim reciting a pharmaceutical containing the oxidized cellulose ester.

The Lee et al patent discloses a carboxylated cellulose ester obtained from oxidized cellulose (see abstract), which anticipates the oxidized cellulose ester of the instant claims. Lee et al also discloses that the cellulose ester may be used in various applications that include pharmaceutical coatings (see column 1, line 16), which anticipates the pharmaceutical of instant Claim 35.

6. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Diamantoglou et al (US Patent No. 5,008,385).

Applicants claim a biodegradable, oxidized cellulose ester. Additional limitations in the dependent claims include: the oxidized cellulose ester having a specific carboxyl content; the oxidized cellulose ester having a specific formula; the oxidized cellulose ester being subjected to specific process conditions and having specific properties such as being dried, being present in a monolithic transparent film, a biodegradable coating, a pharmaceutical, an agricultural product, and a veterinary composition, and being soluble in specific solvents.

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The Diamantoglou patent discloses cellulose derivatives of the formula

wherein the (OZX)_m is deleted when m is selected as 0; t may be selected as 0 or 1, such that when t = 1, Y may be selected as –(CH2)r-COOH, wherein r may be selected as 2; and/or Y may be selected as -CR"=CR"-COOH, wherein R" may be an alkyl; and Y may also be selected as -R', wherein R' may be alkyl; and when t is selected as 0, Y may be selected as -COOR', wherein R' may be hydrogen; n is from 0.01 to 2.95. The above described formula of the Diamantoglou patent anticipates the oxidized cellulose of the instant claims, including the formula set forth in instant Claim 4 when X is H, w is 1; R is -(CH₂)_nCH₃, (CH₂)_nCOOH, wherein n is 1-8, CY=CZCOOH, wherein Y and Z are methyl; and x is 0.1-2.0. Limitations in the instant claims regarding the process step wherein the oxidized cellulose ester is dried is noted, but do not make the claimed oxidized cellulose ester patentable since process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. In re Thorpe et al. (CAFC 1985), supra; In re Dike (CCPA 1968) 394 F2d 584, 157 USPQ 581; Tri-Wall Containers, Inc. v. United States et al. (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; In re-Brown et al. (CCPA 1972) 450 F2d 531, 173 USPQ 685; Ex parte Edwards et al. (BPAI 1986) 231 USPQ 981. Limitations in the instant claims regarding the presence of the oxidized cellulose in a monolithic transparent film, a biodegradable coating, a pharmaceutical, an agricultural product, or a veterinary composition is noted, but do not make the claimed oxidized cellulose ester patentable since a difference in intended use cannot render a claimed composition novel. Note In re Tuominen, 213 USPQ 89 (CCPA, 1982); In re Pearson, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and In re Hack 114 USPQ 161. With regard to the instantly claimed oxidized cellulose ester being biodegradable and soluble in specific solvents, Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art

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teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Accordingly, the above described cellulose derivative of the Diamantoglou patent anticipates the instantly claimed biodegradable, oxidized cellulose ester for the reasons set forth.

Summary

7. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

F White

James O. Wilson

Supervisory Primary Examiner

Technology Center 1600